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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,352	10/08/2003	Kyoji Ogoshi	3190-044	8311
33432 7590 01/07/2009 KILYK & BOWERSOX, P.L.L.C. 400 HOLIDAY COURT SUITE 102 WARRENTON, VA 20186				
EXAMINER				
SIMS, JASON M				
ART UNIT		PAPER NUMBER		
1631				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/681,352

**Applicant(s)**

OGOSHI, KYOJI

**Examiner**

JASON M. SIMS

**Art Unit**

1631

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25, 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's arguments, filed 9/16/2008, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 9/16/2008, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 27-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/12/2007.

Claim 25 is the current claims hereby under examination.

### ***Claim Rejections - 35 USC § 112-First***

#### ***Response to Arguments:***

Applicant's arguments, filed 9/16/2008, with respect to the rejection of claims for lacking enablement under 35 USC 112 first paragraph have been fully considered and are persuasive because of applicant's amendments and arguments. Therefore the rejection has been withdrawn.

**The followings rejection is being newly made, which has been necessitated by amendment:**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment of claim 25 for the step "determining immunotherapy" is found to be new matter not supported by the specification. The specification supports determining anticancer immunotherapy after cancer resection, i.e. Fig. 6, but not any type of general immunotherapy and not at any point in a cancer diagnostic environment.

Furthermore, Claim 25 recites the amended claim wording "wherein the cancer of the patient comprises stomach cancer," which is found to be new matter not supported by the specification. The word "comprises" is open ended claim language and does not exclude additional, unrecited elements or method steps, i.e. other cancers. The specification supports determining anticancer immunotherapy after cancer resection for patients specifically with stomach cancer, but not any other type of cancer.

#### ***Claim Rejections - 35 USC § 112-Second***

##### ***Response to Arguments:***

Applicant's arguments, filed 9/16/2008, with respect to the rejections of claims under 35 USC 112 second paragraph have been fully considered and are persuasive

because of applicant's amendments and arguments. Therefore the rejections have been withdrawn.

**The followings rejection is being newly made, which has been necessitated by amendment:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the wording "determining what amino acids are encoded by positions 57 and 67 of the "HLA DQB1\* gene,"" which is vague and indefinite. It is unclear if the word "positions" refers to the position along the nucleotide sequence comprising the gene or the amino acid sequence comprising the protein, such as that of the translation of the HLA DQB1 gene. The word "positions" is also unclear because it appears to refer to the positions along the nucleotide sequence wherein the word "positions" does not appear to be defined as comprising three nucleotides. Therefore, if the word "positions" refers to places along the nucleotide sequence, it is unclear as to how one position, i.e. one nucleotide, may determine an amino acid sequence. It further appears that the word may read on the amino acid sequence as in the wording of "when Asp is encoded at position 57 and Val is encoded at position 67." However, the wording "of the HLA DQB1\* gene" causes said wording to be vague and indefinite

because the designated positions appear to refer to positions along the gene sequence based on the wording "of the HLA DQB1\* gene." Clarification via clearer claim wording is required.

**The followings rejection is being newly made, which has been necessitated by amendment:**

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-31 are drawn to a process/method. A statutory process must include a physical transformation or recite a tie to another statutory category of invention along with a final resulting step producing a useful, concrete, and tangible result. The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result and a tie to another statutory category of invention.

Claims 25 does not produce a tangible result. A tangible result requires that the claims must set forth a practical application to produce a real-world result. In the instant claims such as claim 25, the final method step comprises a determining immunotherapy to have a statistically significant probability of prolonging the cancer patient's survival, when Asp is encoded at position 57 and Val is encoded at position 67 of the HLA DQB1\* gene, wherein the cancer of the patient comprises stomach cancer. The instant steps read solely on mental steps not necessitating the production of a tangible result.

In addition, because a physical transformation step is not recited in the method Claim 25, critical elements of said method claims are analyzed to determine if they recite a tie to another category of invention. In the instant claims, no step is found that recites a tie to another category of invention and therefore causes said claims to being drawn to non-statutory subject matter (see *In re Bilski*, October 30, 2008).

### ***Claim Rejections - 35 USC § 103***

#### ***Response to Arguments:***

Applicant's arguments, filed 9/16/2008, with respect to the rejection of claims have been fully considered and are persuasive because of applicant's amendments and arguments. Therefore the rejection under 35 USC 103 has been withdrawn.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //  
/Michael Borin/  
Primary Examiner, Art Unit 1631